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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,970	03/28/2002	Alexander Fred Markham	9052-87	8326

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/913,970	MARKHAM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Daniel M Sullivan	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7, 9, 11, 12, 14 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11, 12, 14, 25-27 and 31-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is a reply to the Paper filed 27 October 2004 in reply to the Non-Final Office Action mailed 27 May 2004. Claims 9, 11, 12, 14, 25-27 and 31-46 were withdrawn from consideration and claims 1-4, 7 and 28-30 were considered in the 27 May Office Action. Claims 1, 2, 7, 25 and 28 were amended in the 27 October Paper. Claims 1-4, 7, 9, 11, 12, 14 and 25-46 are pending and claims 1-4, 7 and 28-30 are presently under consideration.

### ***Response to Amendment***

#### Claim Rejections - 35 USC § 112

Claims 1-4, 7 and 28-30 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and herein below in the response to arguments.

Rejection of claims 1-3, 4, 7 and 28-30 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in view of the limitation of the nucleic acid of the claims to at least 95% homology with SEQ ID NO: 1 or to being complementary to SEQ ID NO: 1 and active as a latency promoter.

Rejection of claims 2 and 28 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendments to the claims.

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Claim Rejections - 35 USC § 102

Claims 1-3, 4, 7 and 28-30 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nicholas *et al.* (1992) *Virol.* 188:296-310 as evidenced by Entrez Nucleotide Database Accession No. M86409 for reasons of record and herein below in the response to arguments.

***Response to Arguments***

Claim Rejections - 35 USC § 112

Claims 1-4, 7 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The previous Office Action asserts that the skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of any nucleic acid nucleic acid having at least 75% homology to SEQ ID NO: 1 and “essentially the same biological properties as the disclosed latency promoter”, or any naturally occurring allelic variant of the disclosed nucleic acid. Therefore, only the described nucleic acid comprising at least 630 base pairs of sequence immediately upstream of the initiation codon of ORF73 as set forth in SEQ ID NO: 1 meet the written description provision of 35 U.S.C. §112, first paragraph.

In response, Applicant has amended the claims such that the nucleic acid of the claims is limited to comprising or being complementary to a nucleic acid having at least 95% homology with SEQ ID NO: 1 and having the function of a latency promoter.

In the Remarks, Applicant first asserts that it is not necessary that the application exhaustively describe all nucleotide sequences having the recited sequence and essentially the

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same biological properties as the disclosed latency promoter because “ ‘[w]hat is conventional or well-known to one of ordinary skill in the art need not be disclosed in detail’ ”. This argument is not deemed persuasive because, although the art discloses a nucleic acid comprising SEQ ID NO: 1, there is no disclosure of the structural characteristics that confer the function of a latency promoter such that the skilled artisan would be able to distinguish nucleic acids comprised within the genus having 95% homology with SEQ ID NO: 1 and having the function of a latency promoter from those that do not have that function.

Next, Applicant asserts, “it is not necessary or feasible to list all possible sequences having at least 95% sequence homology to the nucleic acid sequence as set forth in SEQ ID NO: 1” and urges that one of ordinary skill would be able to readily envision a genus of nucleotide sequences having the recited level of sequence homology. While Applicant’s point is taken as far as it goes, the basis of the rejection is that the specification fails to describe the genus of nucleic acids having the recited sequence homology and the functional characteristics of a latency promoter. The claim defines a genus of polynucleotides having a certain structural similarity and then seeks to claim those embodiments within that scope having a desired function. However, the skilled artisan would not have viewed the disclosure as demonstrating possession of the claimed genus because there is no disclosure of the structural features that distinguish what is claimed from what is not claimed. An adequate written description of a chemical invention requires a precise definition, such as by structure, formula, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. The instant disclosure fails to provide a precise definition of the claimed nucleic acid because it fails to define the structure of those

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nucleic acids having 95% sequence homology to the nucleic acid sequence set forth in SEQ ID NO: 1 and the function of a latency promoter.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole. Therefore, the claims stand rejected under 35 USC §112, first paragraph, as lacking adequate written description.

#### Claim Rejections - 35 USC § 102

Claims 1-3, 4, 7 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Nicholas *et al.* (1992) *Viol.* 188:296-310 as evidenced by Entrez Nucleotide Database Accession No. M86409.

In response to the *prima facie* case of record, applicant argues that because the sequence disclosed by Nicholas *et al.* is complementary to SEQ ID NO: 1, the art does not anticipate the claims. Applicant argues that the skilled artisan would not appreciate or recognize the claimed latency promoter. Applicant further argues that Nicolas *et al.* assigns no utility to the region disclosed therein and states there is no direct evidence for expression of the ECLF2 and ECLF3 gene products. Applicant cites *In re Ruschig* and alleges that a statement found therein requires that "the prior art must provide 'a guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made.'" Applicant urges that the skilled artisan, working without knowledge of the instant specification would not be in possession of the claimed invention based on the teachings of Nicholas *et al.*

These arguments appear to be aimed at establishing that the disclosure in Nicolas *et al.* is not enabling and, therefore, the disclosure therein does not anticipate the claims. First, Applicant

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is reminded that anticipation under 35 USC §102 does not require that the art teach the skilled artisan a patentable use for the anticipatory product. “In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. *In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992)” (MEPEP 2122; emphasis added). The instant claims are directed to “[a]n isolated nucleic acid which encodes a latency promoter” wherein said nucleic acid comprises SEQ ID NO: 1 or is complementary to SEQ ID NO: 1. As described in the previous Office Action, Nicholas *et al.* teaches a composition containing isolated double stranded DNA, which is demonstrated to comprise a sequence that is 100% complementary to the instant SEQ ID NO: 1. Thus, absent evidence to the contrary, the nucleic acid also comprises a sequence that is identical to SEQ ID NO: 1, *i.e.*, the antiparallel strand. Applicant’s argument that the skilled artisan would not appreciate that the nucleic acid comprises a latency promoter is not persuasive because the function is inherent to the nucleic acid of Nicholas *et al.* There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). See also MEPEP 2112.

Applicant’s arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims stand rejected under 35 USC §102(b) as anticipated by Nicholas *et al.*

### ***Conclusion***

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.  
Examiner  
Art Unit 1636

  
**DAVID GUZO**  
**PRIMARY EXAMINER**